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| 09/733,507      | 12/08/2000  | Hong Wang            | 4810-56910          | 2417             |

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EXAMINER

COLLINS, CYNTHIA E

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1638

DATE MAILED: 09/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

|  |                                      |                                    |  |
|--|--------------------------------------|------------------------------------|--|
| <p align="center"><b>Office Action Summary</b></p> | <b>Application No.</b><br>09/733,507 | <b>Applicant(s)</b><br>WANG ET AL. |  |
|  | <b>Examiner</b><br>Cynthia Collins   | <b>Art Unit</b><br>1638            |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 June 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 16, 17, 19 and 23-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 18, 20-22 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-15, 18, 20-22 and 27 drawn to the cyclin-dependent kinase inhibitor ICK1, in Paper No. 8 is acknowledged. Claims 16-17, 19 and 23-26, and cyclin-dependent kinase inhibitors ICK2, ICN2, ICN6 and ICN7, are withdrawn from consideration as being directed to nonelected inventions.

### ***Information Disclosure Statement***

An initialed and dated copy of Applicant's IDS form 1449, filed December 8, 2000, Paper No. 8, is attached to the instant Office action.

### ***Claim Objections***

Claims 1-5 are objected to because they recite the nucleic acids of nonelected inventions. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15, 18, 20-22 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of modifying development of a plant by transforming a plant with a nucleic acid encoding a plant cyclin-dependent kinase inhibitor polypeptide, and to a transgenic plant comprising a nucleic acid encoding a heterologous cyclin-dependent kinase inhibitor polypeptide.

The specification describes a single a nucleic acid encoding a plant cyclin-dependent kinase inhibitor polypeptide that functions to modify development when expressed in a transformed plant, a nucleic acid of SEQ ID NO:1 encoding the *Arabidopsis* cyclin-dependent kinase inhibitor polypeptide ICK1 (pages 29-34). This does not constitute a substantial portion of the genus that comprises a nucleic acid encoding a plant cyclin-dependent kinase inhibitor polypeptide that functions to modify development when expressed in a transformed plant, or the genus that comprises a nucleic acid encoding a heterologous cyclin-dependent kinase inhibitor polypeptide that functions to modify development when expressed in a transformed plant. The claimed genus encompasses a multitude of different nucleotide sequences and proteins, including those yet to be discovered. The disclosure of a single nucleic acid of SEQ ID NO:1 that encodes a plant cyclin-dependent kinase inhibitor polypeptide that functions to modify development when expressed in a transformed plant does not provide an adequate description of the claimed genus, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus (see Written Description Guidelines, Federal Register, Vol. 66, No. 4, January 5, 2001, pages 1099-1111).

Claims 1-15, 18, 20-22 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of modifying floral development of a plant by transforming a plant with a nucleic acid of SEQ ID NO:1 encoding the *Arabidopsis* cyclin-dependent kinase inhibitor ICK1, wherein the cyclin-dependent kinase inhibitor ICK1 is expressed in petal and stamen primordia to inhibit floral development, does not reasonably provide enablement for a method of modifying development of a plant by transforming a plant with a nucleic acid encoding a plant cyclin-dependent kinase inhibitor, wherein the cyclin-dependent kinase inhibitor is expressed in proliferative tissue to inhibit development of a differentiated tissue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a method of modifying development of a plant by transforming a plant with a nucleic acid encoding a plant cyclin-dependent kinase inhibitor polypeptide operably linked to a constitutive or tissue specific promoter, wherein the plant cyclin-dependent kinase inhibitor polypeptide is expressed in a proliferative tissue to inhibit development of a differentiated tissue, said method including transforming a plant with a nucleic acid encoding a cyclin-dependent kinase inhibitor homologous to ICK1, a nucleic acid encoding an ICK1 cyclin-dependent kinase inhibitor, and a nucleic acid encoding a cyclin-dependent kinase inhibitor 70% identical, when optimally aligned, to ICK1, and said method including the use of an AP3 promoter, a tissue specific promoter at least 90% identical, when optimally aligned, to an AP3 promoter, and a tissue specific promoter that mediates expression in petal or stamen primordia. The claims are also drawn to a transgenic plant comprising a nucleic acid encoding a

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heterologous cyclin-dependent kinase inhibitor polypeptide. Additionally, the claims are drawn to a method of modifying development of a plant by transforming a plant with a nucleic acid encoding a plant cyclin-dependent kinase inhibitor polypeptide wherein the plant cyclin-dependent kinase inhibitor polypeptide is expressed in a proliferative tissue to change the ploidy of a differentiated tissue.

The specification discloses the transformation of *Arabidopsis* and *Brassica* plants with a nucleic acid encoding the *Arabidopsis* cyclin-dependent kinase inhibitor ICK1. The specification discloses that expression of ICK operably linked to the *Arabidopsis* AP3 promoter in petal and stamen primordia inhibits floral development, resulting in male sterility and reduced or absent petals in transgenic *Arabidopsis* plants as compared to wild type plants (page 29 and page 30 Table 1). The specification also discloses that expression of ICK operably linked to the *Brassica rapa* (*B. campestris*) Bgp1 promoter in pollen and tapetum does not affect floral development or fertility in transgenic *Arabidopsis* plants (page 31). Additionally, the specification discloses that expression of ICK operably linked to the constitutive 35SCaMV promoter results in decreased ploidy in mature leaves of transgenic *Arabidopsis* plants as compared to wild type plants (page 33 Table 2). Furthermore, the specification discloses that expression of ICK operably linked to the *Arabidopsis* AP3 promoter in petal and stamen primordia inhibits floral development, resulting in reduced fertility and reduced petal size in transgenic *Brassica napus* and *Brassica carinata* plants (page 33). Finally, the specification discloses that expression of ICK operably linked to the *Brassica rapa* (*B. campestris*) Bgp1 promoter in pollen and tapetum generally does not affect floral development or fertility in transgenic *Brassica napus* plants, except in a few transformants (~4/40) that exhibit high levels of expression (page 34). The specification does not

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disclose nucleic acids encoding cyclin-dependent kinase inhibitors homologous to ICK1 or the effect of their expression in transgenic plants. The specification does not disclose nucleic acids encoding cyclin-dependent kinase inhibitors that are 70% identical to ICK1 or the effect of their expression in transgenic plants. The specification also does not disclose a tissue specific promoter at least 90% identical, when optimally aligned, to an AP3 promoter, or any tissue specific promoter that mediates expression in petal or stamen primordia other than the *Arabidopsis* AP3 promoter.

While one skilled in the art could readily transform a plant with a nucleic acid encoding any plant cyclin-dependent kinase inhibitor, it would require undue experimentation for one skilled in the art to determine which nucleic acid to express and at what level, because the ability of such a nucleic acid to modify development in a transgenic plant is unpredictable. The specification does not provide sufficient guidance for one skilled in the art to determine which nucleic acid to express and at what level, because the specification teaches only one nucleic acid encoding a plant cyclin-dependent kinase inhibitor polypeptide that can modify development when expressed in a transgenic plant. Also, while one skilled in the art could readily transform a plant with a nucleic acid encoding any plant cyclin-dependent kinase inhibitor, it would require undue experimentation for one skilled in the art to determine how to express such a nucleic acid in a manner that would inhibit the development of differentiated tissues other than flowers, or in a manner that would decrease the ploidy of differentiated tissues other than mature leaves, because the specification does not teach how to express a nucleic acid encoding a plant cyclin-dependent kinase inhibitor such that the development of differentiated tissues other than flowers is modified, or such that the ploidy of differentiated tissues other than mature leaves is changed.

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Furthermore, the specification does not provide sufficient guidance for one skilled in the art to identify, without undue experimentation, which nucleic acids homologous to ICK1 or 70% identical to ICK1 could be used to practice the claimed invention, as the specification does not disclose any such nucleic acid that functions to modify development when expressed in a transgenic plant. Likewise, the specification does not provide sufficient guidance for one skilled in the art to identify, without undue experimentation, which nucleic acids comprising a tissue specific promoter at least 90% identical to an AP3 promoter could be used to practice the claimed invention, as the specification does not disclose any such nucleic acid that confers tissue specific expression to an operably linked nucleic acid in a transgenic plant. Promoters, unlike protein encoding sequences, do not have conservative substitutions, and a single base deletion or substitution could ablate promoter activity. Finally, the specification does not provide sufficient guidance for one skilled in the art to identify, without undue experimentation, which nucleic acids comprising a tissue specific promoter that mediates expression in petal or stamen primordia could be used to practice the claimed invention, as the specification does not disclose any such nucleic acid other than the *Arabidopsis* AP3 promoter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15, 18, 20-22 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.



Claim 1 is indefinite in the recitation of "development" of a plant. It is unclear what "development" constitutes - general plant growth? plant differentiation? See claim 18 etc.

Claims 1, 18, 22 and 27 are indefinite in the recitation of "a differentiated tissue". It is unclear what tissues the method inhibits the development of, since any mature plant tissue, such as leaf tissue, stem tissue, floral tissue, root tissue, etc., would be a differentiated tissue.

Claim 2 is indefinite in the recitation of "homologous to". It is unclear in what way the nucleic acid encoding the cyclin-dependent kinase inhibitor is "homologous" - is the homology structural ? functional ? both ? It is also unclear whether the homology is to the nucleic acid, the cyclin-dependent kinase inhibitor, or both.

Claims 4 and 10 are indefinite in the recitation of "optimally aligned". It is unclear in what way the alignment is optimal, since the characteristic to be optimized is not recited.

Claim 13 is indefinite in the recitation of "modified". It is unclear whether the modification of claim 13 is in addition to the modification of claim 1, or whether the modification of claim 13 is a result of the method of claim 1.

Claim 14 is indefinite in the recitation of "altered", because altered is a relative term that lacks a comparative basis, and because it is unclear what type of petal alteration the method results in, as many different petal characteristics may be altered, such as color, size, shape, number, etc.

Claim 15 is indefinite in the recitation of "wherein the heterologous nucleic acid is introduced into the transgenic plant, or an ancestor of the transgenic plant by the method of claim 1". It is unclear whether "a heterologous nucleic acid encoding a cyclin-dependent kinase inhibitor" is introduced into a plant that already comprises another transgene, or whether "a

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heterologous nucleic acid encoding a cyclin-dependent kinase inhibitor" is introduced into a nontransgenic plant that then becomes transgenic. It is also unclear whether "a heterologous nucleic acid encoding a cyclin-dependent kinase inhibitor" is introduced into an ancestor of the transgenic plant produced by the method of claim 1, or whether "a heterologous nucleic acid encoding a cyclin-dependent kinase inhibitor" is introduced by the method of claim 1 into an ancestor of some transgenic plant. Also, does "capable of" refer the polypeptide, or to the nucleic acid ?

Claim 20 is indefinite in the recitation of "derived". It is unclear what is retained in the derived product. It is suggested that the claim be amended to recite "obtained" instead of "derived".

Claim 27 is indefinite in the recitation of "to change the ploidy", because change is a relative term that lacks a comparative basis, and because it is unclear what type of ploidy change the method results in, as different types of ploidy are possible, such as hyperploidy, hypoploidy, aneuploidy, etc.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 9, 15, and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by John (U.S. Patent Number 5, 750, 862, May 12, 1998).

The claims are drawn to a method of modifying development of a plant by transforming a plant with a nucleic acid encoding a plant cyclin-dependent kinase inhibitor polypeptide operably linked to a constitutive or tissue specific promoter, wherein the plant cyclin-dependent kinase inhibitor polypeptide is expressed in a proliferative tissue to inhibit development of a differentiated tissue in the plant, and to a transgenic plant or plant tissue comprising a nucleic acid encoding a heterologous cyclin-dependent kinase inhibitor polypeptide that is expressed in a proliferate tissue to inhibit development of a differentiated tissue.

John teaches a method of modifying development of a plant by transforming a plant with a heterologous nucleic acid encoding the cyclin-dependent kinase inhibitors WEE-1 or MIK1 operably linked to a constitutive or tissue specific promoter (column 2 lines 1-7, lines 26-30, lines 54-64; column 3 lines 28-32; column 4 line 32, lines 41-65). Nucleic acids encoding the cyclin-dependent kinase inhibitors WEE-1 or MIK1 operably linked to a constitutive or meristem specific promoter would inherently be expressed in a proliferative tissue, and would inherently inhibit development of a differentiated tissue in the plant, since development of differentiated tissue is dependent on cyclin-dependent kinase activity. John also teaches transgenic plants or plant tissue comprising heterologous nucleic acids encoding the cyclin-dependent kinase inhibitors WEE-1 or MIK1 (column 5 lines 49-56; columns 13-14 claims 1-4). The tissues of such plants would include flowers and seed, as John teaches transformation of monocots and dicots (column 2 lines 58-64; column 14 claims 2 and 3).

***Remarks***

No claim is allowed.

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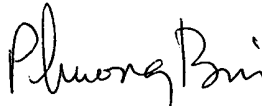
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210.

The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
September 8, 2002

  
PHUONG T. BUI 9/9/02  
PRIMARY EXAMINER